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Docket No.: 02994/100F606-US1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Karen L. Breiges et al.

Application No.: 09/655,667 Art Unit: 3626

Filed: September 6, 2000 Examiner: Natalie Pass

For: CLINICAL TRIAL MANAGEMENT SYSTEM

APPELLANT'S REPLY TO EXAMINER'S ANSWER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Examiner's Answer dated July 7, 2004, Appellant addresses the Examiner's assertions in the order of the sections in which they appear in Appellant's Brief and the Examiner's Answer.

Preliminarily, in the "Response to Argument" section the Examiner often repeats arguments made in both the "Grounds of Rejection" section of the Examiner's Answer and in the final Office Action. In the interest of brevity, at times Appellant does not readdress these same arguments, but does continue to maintain the positions taken in the Appeal Brief.

A. All Claims: None of the applied references suggests the design of a clinical trial, let alone a clinical trial based on templates created from a protocol of tasks to be completed based on old clinical trials (Issues 1-4):

As asserted in the Appeal Brief, none of the applied references teaches or suggests the design of a clinical trial, as required by each of the claims.

Aside from repeating arguments previously made in both the "Grounds of Rejection" section of the Examiner's Answer and the final Office Action, the Examiner responds in the "Response to Arguments" section on page 28, lines 3-8, by stating that Colon discloses "a main database of information concerning prior clinical trials and resources available to conduct future clinical trials ...." In fact, Colon discloses a database of information on the single clinical trial of interest. It has no information concerning future clinical trails. For example, if the current trial is the delivery of drug A in certain quantities to people with certain conditions at certain times, there is no provision in Colon to know if drug B is available, for a trial of it with different people. While DeBusk may show resources available to a hospital, they are not related in any way to a clinical trial.

In the Response to Arguments section on page 28, lines 15-17, the Examiner states that there is nothing in the claim language of independent claims 1, 19, and 34 that precludes the use of this system[1] for an existing clinical trial. Appellant respectfully disagrees. First, the Examiner's statement is irrelevant to the issue of the patentability of the claims. The question is not whether a system as defined in the specification and claims can be used for an existing clinical trial, it is whether the prior art discloses its use for the creation of a new clinical trial. As indicated, it does not. Second, the present claims do require the creation of a clinical trial, which the prior art must disclose to defeat the patentability of those claims. In particular, claim 1 requires a "user processor and main processor running a program that designs ... a clinical trial ... and modification of [a] template for formulating a new clinical trial." Claim 19 requires a "user processor and main processor running a program that designs a clinical trial in the form of a protocol of tasks" and a "subsidiary processor and subsidiary user processor running the program so as to design ... a

[1] By "this system," Appellant assumes the Examiner is referring to the system as claimed in the independent claims.

protocol." Claim 43 requires a "user processor and main processor running a program that designs a clinical trial." Thus, rather than the conduction of an existing clinical trial, each of the claims is clearly directed to the design of a clinical trial. The Examiner's position that the claimed invention could be used for an existing clinical trial is irrelevant and it is clear that the claims do require the creation of a new clinical trial. The fact alone that none of the references disclose the design of a clinical trial, which is an element of all of the claims and is an important element of the invention, all of the claims are patentable.

The Examiner also asserts on page 28, lines 17-20, of the Examiner's Answer that she interprets Colon's statements that Colon's "'invention allows larger studies to be conducted ...' and '... [manages] data used in conducting clinical studies ...' ... as reading on designing or setting up and running a clinical study or clinical trial (Colon, column 1, lines 60-63, Abstract)." Appellant respectfully disagrees. The language the Examiner identifies in Colon relates to "conducting" clinical trials and has nothing to do with "designing" a clinical trial, as required by the claimed invention. The computer system of Colon, since it allows for some tasks previously performed by hand to be done automatically, allows for the manual design of larger clinical trials of which the Colon system can keep track.

The Examiner also references, in the paragraph bridging pages 28 and 29 of the Examiner's Answer, numerous portions of Colon as allegedly reading on a "[protocol][2] of a prior clinical trial being stored in a database." In particular, the Examiner refers to data stored in a database that "is controlled according to scientifically developed mathematical and statistical methods" and has "consistent operation ... across all activities." However, mathematical and statistical methods and

[2] The Examiner wrote "standardization," but the claim language is actually "protocol."

consistent operation is not at all the same as a prior clinical trial. These concepts are so different that further explanation here is deemed unnecessary. At most, Colon discloses using "input forms developed for the specific clinical study." Col. 1, line 65. However, an input form is not a protocol or a template for a clinical trial. Further, the input form is for a specific clinical study, not a form to be used for past and future trials.

The Examiner also refers on page 29, lines 7-14, of the Examiner's Answer, to portions of DeBusk as allegedly teaching "stored in a database in the form of a software template based on old clinical trials." As asserted in the Appeal Brief, DeBusk relates to an information management system providing customized management of the use of medical resources using user-configured software modules. DeBusk does not relate to clinical trials, not to mention old clinical trials.

Furthermore, the Examiner asserts in the last full paragraph of page 29 of the Examiner's Answer that since Colon and DeBusk each reference a new study, then they must include the design of the study. Again, DeBusk relates to an information management system and has nothing to do with a study (i.e., clinical trial). Colon relates to the conduction of an already-designed clinical trial. Colon does not relate to the design of a new clinical trial. To the extent Colon refers to a new study, it is a manually developed clinical trail which is presented to the Colon system, not one designed on the Colon system using protocols and templates.

Finally, the Examiner also asserts in the last full paragraph on page 29 of the Examiner's Answer that "there is no component in the claim language of claims 1, 19, or 43 that actually performs the designing, but rather a processor running a program that designs and tracks." Appellant disagrees with the Examiner's assertion. As admitted by the Examiner in the same statement, the component that performs the designing is the processor running the program. Again,

none of the applied references, either alone or in combination, suggests the design of a clinical trial, as required by each of the claims.

B. Claim 1: DeBusk does not teach the protocol[3] of a prior clinical trial being stored in a database in the form of a software template (Issue 1)

Appellant asserted in the Appeal Brief that DeBusk does not teach the protocol of a prior clinical trial being stored in a database in the form of a software template. Despite the fact that the Examiner admits on page 6 of the "Grounds of Rejection" section that "Colon fails to explicitly disclose the protocol of a prior clinical trial being stored in said main database in the form of a software template," the Examiner asserts on page 30 of the "Response to Argument" section that the combination of Colon and DeBusk teaches this feature, and on pages 30-31 refers Appellant to a multitude of places in both Colon and DeBusk that allegedly combine to teach this feature.

In Colon, the Examiner refers to data being stored in database tables used for statistical analysis and automatic assignment of participants in clinical studies and that "is controlled according to scientifically developed mathematical and statistical methods" (Colon, col. 1, lines 50-53) and "consistent operation ... across all activities" (Colon, col. 7, lines 66, through col. 8, line 1). The Examiner's quotes from Colon do not at all relate to the protocol of a prior clinical trial being stored in a database in the form of a software template. The first quote relates to the conduction of clinical trials, which could be a form of protocol, but is definitely not a template. And the second quote is taken out of context; the "consistent operation and access across all activities" relates to management data and other study data being stored in the same database, and has nothing to do with prior clinical trials or software templates.

[3] In the Appeal Brief, Appellant used the word "standardization" but actually intended to use the word "protocol," which is recited in claim 1.

Regarding DeBusk, Appellant respectfully submits that DeBusk relates to an information management system providing customized management of the use of medical resources (e.g., doctor time, equipment, and supplies) using user-configured software modules. Hospitals and health-care providers can buy an off-the-shelf software product that, through the use of the software modules, may be tailored to the facility's individuals needs. DeBusk does not at all relate to clinical trials. Each of the Examiner's quotes from DeBusk supports Appellant's characterization of DeBusk, which does not in any way teach or suggest the protocol of a prior clinical trial being stored in a database in the form of a software template, as required by claim 1. For example, the Examiner quotes DeBusk as teaching "software module objects ... [that] ... are user created objects which represent individual templates ..." that "allow for the development of custom software modules representative of the procedure for which information is to be managed." The Examiner then provides a long quote from DeBusk which basically states that modules of previous cases can be used to analyze utilization. An example of such a module could be heart bypass surgery, which would provide a ready listing of resources to be used during the procedure. Creating a case module allows for easy tracking of resource utilization and creates a consumption record of resources used during the procedure. Again, DeBusk relates to tracking medical resource use, and does not relate to clinical trials.

Furthermore, the Examiner responds to Appellant's argument that DeBusk does not teach the protocol of a prior clinical trial being stored in a database in the form of a software template, by stating that in DeBusk, "the user may create the various container, resource and data objects that will be used to create the module representing a clinical pathway. Alternatively, the user may select such objects from pre-configured libraries of such objects or by copying such objects from clinical

pathways already created." (See DeBusk, col. 8, lines 21-27.) The Examiner then concludes that DeBusk teaches the creation of and selection of modules or templates. See Examiner's Answer, page 31, first full paragraph. Even assuming the Examiner's position is correct, DeBusk still does not teach or suggest a protocol of a prior clinical trial being stored as a template, as required by claim 1. DeBusk's container, resource and data objects relate to a medical procedure. More specifically, a container object functions as a container for additional container, resource or data care events. An example of a container object is an anesthesia care event 214. A resource object 224 contains resources such as anesthesia drugs. An example of a data object 220 is a patient history. (See DeBusk, Fig. 2 and col. 13, lines 15-56.) These objects relate to a medical procedure to be conducted, not a protocol of a prior clinical trial, let alone a template for one.

Furthermore, the Examiner again asserts in the last full paragraph of page 31 of the Examiner's Answer that since Colon and DeBusk reference new studies, then they must include the design of the study. As asserted above in section A, DeBusk relates to an information management system and has nothing to do with a clinical trial. Colon relates to the conduction of an already-designed clinical trial; it does not relate to the design of a clinical trial, particularly in the manner defined by the claims of the present invention.

Finally, the Examiner again asserts that "there is no component in the claim language of claims 1, 19, or 43 that actually performs the designing, but rather a processor running a program that designs and tracks." As discussed above in section A, the Examiner admits in this same statement that the component that performs the designing is the processor running the program. Again, none of the applied references, either alone or in combination, suggests the design of a

clinical trial, let alone a clinical trial based on templates created from a protocol of tasks to be completed based on old clinical trials, as required by claim 1.

C. Claims 6 and 7: Colon does not teach a main processor and main database in an organizational environment that includes other databases with information for formulating clinical trials (Issue 1)

As asserted in the Appeal Brief, Colon does not teach a main processor and main database in an organizational environment that includes other databases with information for formulating clinical trials, as required by claims 6 and 7. In the "Response to Argument" section of the Examiner's Answer, the Examiner repeats arguments made in both the "Grounds of Rejection" section of the Examiner's Answer and in the final Office Action. These arguments were addressed in the Appeal Brief, and for the sake of brevity, will not be repeated here.

Further, in response to Appellant's argument that Colon relates to the conduction of an already-designed clinical trial, and thus has no need for databases with information for formulating clinical trials, the Examiner asserts in the last paragraph of page 32 of the Examiner's Answer that since the Colon and DeBusk references allegedly teach a new clinical trial, the design of the trial is inherently included. Again, DeBusk relates to an information management system and has nothing to do with a clinical trial. And even though Colon may relate to the conduction of an already-designed clinical trial, it does not include a processor running a program that designs a clinical trial in the manner defined by the claims of the present invention.

The Examiner then goes on to assert that there is allegedly "no component in the language of system claims 6 or 7 that actually performs the formulating, but rather the storing in databases of 'specialized information useful in formulating clinical trials.'" Although there is no requirement that the claims recite a component that actually performs the formulating, claims 6 and 7 do recite

such an element. More specifically, claims 6 and 7 depend from claim 1, which recites the "user processor and main processor running a program that designs ... a clinical trial," and thus claims 6 and 7 do in fact have a component that performs the formulating. Moreover, claims 6 and 7 recite databases with information for formulating clinical trials; this feature is not suggested by the applied prior art, and thus claims 6 and 7 are patentable for this additional reason.

The Examiner then asserts on the top of page 33 of the Examiner's Answer that "there is nothing in the claim language of claims 6 and 7 that precludes use of this system or of these databases for an existing clinical trial." Appellant respectfully disagrees. First, the issue as presented by the Examiner is irrelevant to patentability of the claims. That the system of the present invention can manage an existing clinical trial does not mean that the prior art discloses the creation of a new clinical trial from templates as required by the present claims. In particular, claim 1, from which claims 6 and 7 depend, requires a "user processor and main processor running a program that designs ... a clinical trial ... and modification of [a] template for formulating a new clinical trial." Thus, rather than the conduction of an existing clinical trial, each of the claims is clearly directed to the design of a clinical trial. Thus, the Examiner's position that the invention as defined by claims 6 and 7 could be used for an existing clinical trial is irrelevant and it is clear that these claims specifically require the creation of a new clinical trial.

The Examiner asserts in the first full paragraph on page 33 that she disagrees with Appellant's assertion that the Examiner pulled two halves of a quote from completely separate portions of Colon, and completely misrepresents the Colon's teachings. Appellant has re-reviewed the quote and stands by Appellant's position. Although the Examiner states that the language was taken from Colon, col. 2, line 58, though col. 3, line 34, the language is in fact taken from col. 2,

lines 59-61 and the Abstract. In any event, Colon, even in combination with the other references, still does not suggest the claimed invention.

The Examiner also repeats the argument that the claims do not recite "a component that actively formulates a clinical trial." Appellant disagrees for the reason previously stated above, that is, claims 6 and 7 depend from claim 1, which recites the "user processor and main processor running a program that designs ... a clinical trial," and thus claims 6 and 7 do in fact have a component that formulates a clinical trial.

D. Claim 43 does not differ from claim 19 in the manner suggested by the Examiner (Issue 1)

Appellant thanks the Examiner for withdrawing the statement regarding the alleged differences between claims 19 and 43. Appellant still maintains, however, that claims 19 and 43 are patentable over the applied references for reasons discussed throughout the Appeal Brief and this Reply.

E. Claims 43 and 44: neither Colon nor DeBusk suggests the input of information with regard to completion of tasks and tracking the completion at a user processor (Issue 1)

In response to Appellant's argument that neither Colon nor DeBusk suggests the input of information with regard to completion of tasks and the tracking of the completion of the tasks of a clinical trial at a user processor, as required by Claims 43 and 44, the Examiner, in the "Response to Argument" section on page 34, repeats arguments made in both the "Grounds of Rejection" section of the Examiner's Answer and in the final Office Action. Then in the paragraph bridging pages 34 and 35, the Examiner provides an additional quote from DeBusk. The quote basically states that DeBusk allows a user to configure software modules to track the provision of health care, as well as the utilization and allocation of resources for medical procedures in order to enhance efficiencies

related to the provision of medical procedures. The Examiner interprets the DeBusk quote as reading on the input of information with regard to the completion of tasks and tracking completion at the user processor. Appellant respectfully disagrees. The DeBusk system provides a user with the ability to custom design a program to document the provision of health care resources. In other words, when resources are used, the use is documented in the system so that the information can be later analyzed and improvements made in the provision of labor, equipment, supplies, etc. Thus, in DeBusk the program does not require in advance of a procedure that any particular resources be used; DeBusk merely allows a user to document resources used because they were necessary at the time of the procedure. The claimed invention, on the other hand, involves preassigned tasks to be performed in order to conduct a clinical trial. Thus, DeBusk's documentation of medical resources is different than the claimed input of information with regard to completion of tasks, which are inherently preassigned, and the tracking of the completion at a user processor, as required by claims 43 and 44.

F. Claims 2 and 19: Colon and DeBusk also do not suggest a program that permits the design of a clinical trial in the form of a protocol of tasks to be completed and does not track the completion of the tasks in the protocol at a user processor (Issue 2)

In response to Appellant's argument that Colon and DeBusk do not suggest a program that permits the design of a clinical trial in the form of a protocol of tasks to be completed and does not track the completion of the tasks in the protocol at a user processor, as required by Claims 2 and 19, the Examiner refers to numerous portions of Colon and DeBusk. As asserted previously, the applied references do not suggest the design of a clinical trial, and the portions of Colon and DeBusk to which the Examiner refers support Appellant's position. Colon relates to the conduction of an already-designed clinical trial. During the trial a doctor inputs patient data into standardized

forms, and the data is subsequently analyzed. And DeBusk relates to an information management system providing customized management of the use of medical resources using user-configured software modules. Hospitals and health-care providers can buy an off-the-shelf software product that, through the use of the software modules, may be tailored to the facility's individuals needs. Since Colon and DeBusk do not relate to the design of a clinical trial in the form of a protocol of tasks to be completed and do not track the completion of the tasks in the protocol at a user processor, claims 2 and 19 are patentable over the applied prior art.

Additionally, the Examiner asserts in the last paragraph of page 37 of the Examiner's Answer that since Colon and DeBusk reference new studies, they must include the design of the study. Again, DeBusk relates to an information management system and has nothing to do with a clinical trial. And even though Colon may relate to the conduction of an already-designed clinical trial, it does not relate to the design of the clinical trial in the manner defined by the claims of the present invention.

Furthermore, the Examiner again asserts that "there is no component in the claim language of claims 2 (which depends on claim 1) or 19 that actually performs the designing, but rather a processor running a program that designs and tracks." As discussed above in section A, the Examiner admits in this same statement that the component that performs the designing is the processor running the program.

G. Claims 5 and 22: Edelson does not suggest a main processor and a subsidiary processor periodically operating to synchronize replicated and changed data at the main database and the subsidiary database with changes at said main database predominating over changes at said subsidiary database (Issue 2)

As asserted by Appellant in the Appeal Brief, Edelson does not suggest a main processor and a subsidiary processor periodically operating to synchronize replicated and changed data at the

main database and the subsidiary database with changes at the main database predominating over changes at the subsidiary database. Unlike the present invention, Edelson cannot synchronize replicated and changed data at the source database and the remote databases as described in the claims. Although the data is synchronized, it is replicated only at the source database; the data at the remote database is read-only and thus can not be changed during synchronization so the source database can predominate. (See Edelson, column 48, lines 5-7.)

The Examiner responds on page 38 of the Examiner's Answer by repeating her previous references to Edelson and alleging that "the remote data is only maintained as read-only for remote access at times that the synchronization is not taking place." Appellant agrees that the source data at the point of care computer 201 and the remote database 210, or main database 212 can both be updated when synchronization is not being performed. The remote database is "read-only" during synchronization, but otherwise data may be entered into it. Col. 48, lines 5-31. However, since the remote database is read only during synchronization, the main database 212 cannot predominate over changes at the remote database. Thus, there is no support in Edelson for the Examiner's position. Edelson states that each data warehouse 212 (i.e., main database) maintains replicated copies of relevant data sets obtained by read-only access of remote databases 210 (i.e., subsidiary databases). Thus data is replicated at the main database from the subsidiary databases. Data is not also replicated at the subsidiary databases, as required by claims 5 and 22. Since data is not replicated at the subsidiary database during synchronization, it necessarily follows that the main database can not predominate over changes at the subsidiary databases, as also required by claims 5 and 22.

H. Claims 15, 16, 32, and 33: Applied references do not suggest a site management module for indicating conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location (Issue 2)

The applied references do not suggest a site management module for indicating conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location, as required by claims 15, 16, 32, and 33. Because of varying local laws, a plan for a clinical trial might need to be different in different geographical regions. But the data must still be maintained sufficiently uniform so that it can be combined in the total trial results.

Colon merely discloses conducting a trial with subjects located at different geographic sites. While Colon does mention that its system has information about regions (col. 5, line 22-24), there is no disclosure that the protocol varies from location to location, so there is no need to indicate a portion of any protocol to be carried out in any particular geographical location.

DeBusk does not relate to clinical trials, and thus there is no trial protocol involved. As stated previously, DeBusk relates to a health care information management system to track utilization of resources at a medical facility. DeBusk discusses a difference between inside and outside resources needed for a medical procedure within a facility, but there is no suggestion of a clinical trial protocol.

Edelson also does not relate to clinical trials. Edelson relates to a prescription creation system. While patients and medical facilities may be in different geographical locations, there is no disclosure of clinical trial protocols, not to mention trial protocols varying between geographical locations. Thus, like Colon and DeBusk, Edelson does not suggest a site management module for indicating conditions at the certain geographical location, including the portion of any protocol to be carried out in that geographical location, as required by claims 15, 16, 32, and 33.

I. Claims 16 and 33: Neither Colon nor DeBusk suggests that information about the completion of tasks in the protocol at a certain geographical location are entered by a subsidiary user processor in a subsidiary database, and a site management module updates a portion of the protocol related thereto (Issue 2)

As asserted by Appellant in the Appeal Brief, neither Colon nor DeBusk suggests information about completion of tasks in a protocol at a certain geographical location being entered by a subsidiary user processor in a subsidiary database, and a site management module updating a portion of the protocol related thereto, as required by Claims 16 and 33.

The Examiner responds on pages 41-43 of the Examiner's Answer by citing portions of Colon and Edelson. Regarding Colon, as stated in the previous section H, Colon merely discloses conducting a trial with subjects located at different geographical sites. There is no disclosure that protocol varies from location to location. There is therefore no need for Colon to update a portion of the protocol related a certain geographical location.

In Edelson the Examiner cites a portion that involves creating a new prescription and transmitting it across a network. Edelson does not relate to clinical trials. While a prescription record in Edelson may be updated after a prescription is filled, there is no change in a protocol of a clinical trial, not to mention a trial protocol in a certain geographical location. Thus, like Colon, Edelson does not suggest the features of claims 16 and 33.

J. Claims 17 and 34: Edelson does not suggest transferring from a main processor to a portable processor a copy of a portion of a main database related to a site for a clinical trial in a certain geographical area, the main processor locking the portion of the main database that was copied, the portable processor receiving information about the completion of tasks in the protocol at the certain geographical area and modifying the copy as a result thereof, and the portable processor transferring to and updating the main database with the modified copy of the data and unlocking that portion of the main database (Issue 2)

Edelson does not suggest transferring from a main processor to a portable processor a copy of a portion of a main database related to a site for a clinical trial in a certain geographical area, the main processor locking the portion of the main database that was copied, the portable processor receiving information about the completion of tasks in the protocol at the certain geographical area and modifying the copy as a result thereof, and the portable processor transferring to and updating the main database with the modified copy of the data and unlocking that portion of the main database, as required by claims 17 and 34.

Appellant asserted in the Appeal Brief that Edelson does not teach locking and unlocking portions of databases. The Examiner responds on page 43 of the Examiner's Answer by stating that "Edelson teaches data that is 'preferably either synchronized or refreshed at intervals (e.g. overnight) from source databases." The Examiner also states that Edelson teaches that "'[e]ach data warehouse 212 maintains replicated copies of relevant data sets obtained by read-only access of remote databases 210, which data sets are maintained synchronously with updated source data at remote databases 210, or are periodically refreshed therefrom, preferably at frequent intervals.'"

But contrary to the Examiner's position, synchronizing data at intervals is not the same as locking and unlocking the database. Synchronizing data at regular intervals is merely updating the data regularly. Locking/unlocking a database is denying/permitting access to the data. Merely because during the time between intervals data is not being updated does not mean that the database

is locked. By way of analogy, merely because people are not going in or out of a house through the front door doesn't mean the door is locked. Also, the fact that Edelson's remote database is read-only access is irrelevant because the claims recite a main database rather than a remote database is locked.

K. Claim 44: Edelson does not suggest replicating to a subsidiary database a portion of data relating to clinical trials in a certain geographical location (Issue 2)

Edelson does not suggest a portion of data in a main database and relating to clinical trials in a certain geographical location being replicated to a subsidiary database, as required by Claim 44. Rather, Edelson states in column 48, lines 5-7, that each data warehouse (i.e., main database) maintains replicated copies of data sets obtained by read-only access of remote databases (i.e., subsidiary database).

The Examiner responds on page 45 of the Examiner's Answer by stating that Appellant's assertion that the remote database is read-only is taken out of context. The Examiner asserts that "the remote data is maintained as read-only for remote access at times that the synchronization is not taking place." The Examiner's argument is misplaced. In Edelson the data warehouses 212 do not replicate data to the remote databases 210 (i.e., subsidiary databases). The remote databases 210 are updated, but locally; and then the data in the remote databases 210 is sent to the data warehouses 212, not visa versa. See Edelson, col. 48, lines 5-24. Claim 44, on the other hand, requires replicating data from a main database to a subsidiary database.

L. Claims 25-27 and 29-31: Umen does not suggest displaying at a user processor and subsidiary user processor which are operative to display a clinical trial protocol, a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task (Issue 3)

Appellant maintains that Umen does not suggest displaying at a user processor and subsidiary user processor which are operative to display a clinical trial protocol, a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task. Umen merely displays a tabular list of protocols, with none of the protocols indented. (See Umen, col. 10, lines 23-31.)

The Examiner again asserts on page 45 of the Examiner's Answer that Umen teaches this feature with Umen's statement that a management user interface displays a tabular list 66 of protocol and results details. (See Umen, col., 10, line 26). However, this statement does not include displaying a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task, as required by the claims. The Examiner also refers to Umen's general protocol information report and detail entry reports, which are shown in Figs. 5-7. However, these reports do not list visits forming a protocol, not to mention minor tasks indented under major tasks.

The Examiner also references on page 46 of the Examiner's Answer portions of Colon and Edelson. In Colon the Examiner references the basic database tables of Fig. 4, and in Edelson the simple drug lists shown in Fig. 8, but these references do not suggest the claimed feature. Neither Colon nor Edelson suggests displaying a clinical trial protocol, and a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task, as required by claims 25-27 and 29-31.

M. Claims 10 and 45: None of the applied references suggests the program automatically indicating the completion of a common major task in separate protocols when all of the minor related tasks are completed (Issues 3 and 4)

None of the applied references suggests a program that automatically indicates the completion of a common major task in separate protocols when all of the minor related tasks are completed.

The Examiner asserts that Edelson teaches this feature with Edelson's disclosure that the "system also provides, for example in the patient's history record, notification from a pharmacy, or from a drug benefit plan linked to the pharmacy, of fulfillment of a prescription." (See Edelson, col. 27, lines 47-50). The Examiner explains that she interprets "notification of the fulfillment of a prescription as the completion of a minor task, with the major task being the updating of the patient history record."

Appellant respectfully disagrees with the Examiner's position. Claims 10 and 45 require automatically indicating completion of a common major task in separate protocols when all of the minor related tasks are completed. In other words, there is a common task that occurs in more than one protocol, and there is an indication when it is completed in each of the separate protocols. Under the Examiner's logic, if the major task is the patient history record, then this record would have to appear in separate protocols. Since Edelson does not relate to clinical trials, it does not teach protocols. The Examiner logic is therefore flawed, and claims 10 and 45 are patentable over the applied references.

N. Prior Art Rejections (Issues 1-4)

In section N of the Examiner's Answer the Examiner repeats assertions asserted in previous sections. Since these assertions have already been addressed, no repeat response is believed necessary here.

Moreover, the Examiner has made a substantial number of assertions throughout the 19-page final Office Action dated February 6, 2004 and throughout the 50-page Examiner's Answer dated July 7, 2004, particularly with regard to the how the applied references allegedly read on the pending claims. Applicant has responded to as many of these assertions as practical. The lack of an explicit response to any of these assertions should not be deemed as an implied admission by Appellant of its merits.

O. Claims 35 and 36 are sufficiently definite (Issue 5)

Appellant thanks the Examiner for agreeing that claims 35 and 36 are sufficiently definite and for withdrawing the § 112 rejection.

Appellants respectfully request that the application be remanded to the primary Examiner with an instruction to withdraw the § 103 rejections and pass the case to allowance.

Please charge any fee, except for the Issue Fee, that may be necessary for the continued pendency of this application to our Deposit Account No. 04-0100.

Dated: August 3, 2004

Respectfully submitted,

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Appellant's Reply to Examiner's Answer (21 pages)
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